# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte C. ALEXANDER TURNER, JR. and BRIAN MATHUR



Appeal No. 2005-2387
Application No. 09/714,883

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3, all of the claims in the application. Claim 3 is representative and reads as follows:

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2.

The examiner does not rely on any references.

Claims 1-3 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

Background

The specification discloses "human polynucleotides encoding proteins that share sequence similarity with mammalian ceruloplasmins. . . . Ceruloplasmins are members of a family of metal chelating proteins." Page 1. Ceruloplasmin is "the major copper transporting protein in plasma." Chowrimootoo,[1] page F198. "Ceruloplasmins have been associated with development, ferroxidase activity, amine oxidase activity, copper transport, homeostasis, and superoxide dismutase activity." Specification, page 1.

Appellants assert that the protein encoded by the claimed nucleic acids shares 57% identity with human ceruloplasmin. Appeal Brief, page 4. The specification discloses that the encoded protein can be used "for the treatment of Wilson's disease, etc." Page 12. "Wilson's disease is an inherited disorder of copper metabolism, with impairment of biliary copper excretion, resulting in copper accumulation in the liver and consequent damage. There is also a variable reduction in, or absence of, circulating caeruloplasmin." Chowrimootoo, page F198. "[T]here are two molecular isoforms, one predominating in bile (125 kiloDaltons) and the other in plasma (132 kiloDaltons). The biliary form is always absent in Wilson's disease bile and may be important in copper excretion." Id.

Besides treating Wilson's disease, the specification asserts other uses for the claimed nucleic acids and the protein encoded thereby. The specification contemplates "processes for identifying compounds that modulate, i.e., act as agonists or antagonists, of NHP ["novel human protein"; i.e., the protein encoded by the claimed nucleic acids]

[1] Chowrimootoo et al., "Caeruloplasmin isoforms in Wilson's disease in neonates," Arch. Dis. Child Fetal Neonatal Ed., Vol. 79, pp. F198-F201 (1998). Chowrimootoo was attached to the Appeal Brief (Exhibit D) and considered by the examiner. See the Examiner's Answer, page 10.

expression and/or NHP activity . . . . Such compounds can be used as therapeutic agents for the treatment of a wide variety of symptoms associated with biological disorders or imbalances." Page 2.

The specification states that "suitably labeled NHP nucleotide probes can be used to screen a human genomic library using appropriately stringent conditions or by PCR. The identification and characterization of human genomic clones is helpful for identifying polymorphisms . . . , determining the genomic structure of a given locus/allele, and designing diagnostic tests." Pages 7-8.

The specification also states that "[t]he NHP proteins or peptides, NHP fusion proteins, NHP nucleotide sequences, host cell expression systems, antibodies, antagonists, agonists and genetically engineered cells and animals can be used for screening for drugs . . . effective in the treatment of the symptomatic or phenotypic manifestations of perturbing the normal function of a NHP in the body." Page 11.

Finally, the specification discloses that a polymorphic position was identified in SEQ ID NO:1: position 1756 can be either G or A, resulting in either Val or Ile at amino acid 586 of SEQ ID NO:2. Page 13.

## Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[2] The examiner bears the initial burden of showing that a

[2] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's Answer, page 7. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The examiner reasoned that the evidence of record does not support concluding that the protein encoded by the claimed nucleic acids will have the same function as ceruloplasmin. See the Examiner's Answer, pages 4-5. The examiner also found that the similarity of the encoded protein and ceruloplasmin "does not make the instant DNA or encoded protein diagnostic of a disease or useful in the treatment of a disease. There is no evidence of record . . . that the instant nucleic acid or encoded protein is associated with any particular disease or disorder. . . . The instant application also fails to demonstrate use of the protein as a marker for any disease or condition, including Wilson's disease, which would be a real world use." Id., pages 5-6.

Appellants argue that the protein encoded by the claimed nucleic acids is 57% identical to human ceruloplasmin. Appeal Brief, page 4. Appellants also argue that "the association between ceruloplasmin and Wilson's disease was discussed in the present application, at least at page 12, lines 1-2, and, further, that this relationship between ceruloplasmin and Wilson's disease has long been recognized by skilled artisans." Id. Appellants urge that "the skilled artisan would readily appreciate the utility associated with the provision of novel human sequences related to ceruloplasmin, and therefore, the present utility rejection must fail." Id., page 5.

We are not persuaded that the relationship between ceruloplasmin and Wilson's disease supports the utility of the claimed nucleic acids. While Chowrimootoo shows that ceruloplasmin is likely to have a role in Wilson's disease, the protein encoded by the claimed nucleic acids is not ceruloplasmin, it is a different protein that is only 57% identical to ceruloplasmin.

Fifty-seven percent identity might be enough to suggest to those skilled in the art that the protein of SEQ ID NO:2 is a metal-binding protein; it might even be enough to suggest that it is a copper-binding protein. The evidence of record is inadequate to support either conclusion, but even if it did, there is no evidence in the record to show that the protein of SEQ ID NO:2 is involved in Wilson's disease. Chowrimootoo teaches that Wilson's disease results in "impairment of biliary copper excretion, resulting in copper accumulation in the liver and consequent damage." Page F198. There is no evidence in the record that the protein of SEQ ID NO:2 has a role in biliary copper excretion, such that its absence would be expected to contribute to the symptoms seen in Wilson's disease, nor is there other evidence in the record to show that the protein of SEQ ID NO:2 is involved in Wilson's disease.

Since there is no evidence in the record that the protein of SEQ ID NO:2 is involved in Wilson's disease, there is no evidence that the protein encoded by the claimed nucleic acids, or antibodies, agonists or antagonists to the protein, would be useful in diagnosing, treating or preventing Wilson's disease. Thus, the relationship between ceruloplasmin and Wilson's disease does not provide a utility for the claimed nucleic acids.

Appellants also argue that the claimed nucleic acids are useful "for assessing gene expression using, for example, DNA chips" (Appeal Brief, page 7); that they are useful in mapping human chromosomes (id., page 8); and that "the described sequences are useful for functionally defining exon splice-junctions" (id., page 9).

We find that none of these uses meet the requirements of § 101. The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 2005 WL 2139421 (Sept. 7, 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 2005 WL 2139421, at *4. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case was either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which

they have been used in the real world." Id. at *7. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at *8.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, as in Fisher, the generic uses – assessing gene expression, mapping human chromosomes, and identifying exon splice-junctions – asserted by Appellants are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 2005 WL 2139421 at *7 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at *8.

Finally, Appellants argue that the identified polymorphism in SEQ ID NO:1 makes the nucleic acids useful in "forensic analysis." Appeal Brief, pages 8-9.

We do not agree that the disclosed polymorphism establishes the utility of the claimed nucleic acids. First, Appellants' argument lacks support in the specification or in the evidence of record. The specification discloses the presence of a polymorphism in SEQ ID NO:1 (page 13) but discloses no utilities based on detection of the polymorphism. In particular, the specification does not disclose that the polymorphism is a useful marker for forensic analysis.

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphism, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world. Cf. Fisher, 2005 WL 2139421 at *7. It is not specific because nothing about the asserted utility sets apart the polymorphism in the claimed nucleic acids from any other polymorphism found in the human genome. Cf. id. at *8.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1-3.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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